REMARKS

Claims 19, 11-19 and 21 are in this application with claims 2, 4, 13, and 15 having been amended and claims 10 and 20 cancelled herein. No new matter has been added by these amendments.

The Examiner has apparently acknowledged in part the amendments to the specification which obviate the prior objections to the drawings. However, the Examiner now invokes the draftsman's review as allegedly clarifying the features which the Examiner does not find in the figures. But other than reiterating the known requirement that formal drawings must be presented prior to issuance, the draftsman's review does nothing to support the Examiner's allegations. In paragraph 2 of the office action the Examiner appears to state that Fig. 5 does not show a flange having two thicknesses on both sides of the flange. The basis for this assertion is unclear at best, but it is believed that the Examiner is somehow confused by the circle indicating the close-up view which is shown as part of Fig. 5. The Examiner attention is again directed to this area as clearly the thickness of the flange in the area circled is greater than the thickness of the flange outside the circle. Moreover, even if still unsure, the Examiner is directed to Fig. 3 where there is no circle for the representation of a highlighted section, and which clearly shows a flange having two different thicknesses thus meeting the limitation of the claim. As both thickness are clear in the figures and the figures and specification have previously been amended to clarify their teachings, it is submitted that the Examiner's apparent objection has been addressed.

The Examiner has objected to certain formalities in claims 2, 4, 13, and 15. These claims have been amended to address the objections of the Examiner. Withdrawal of these objections is requested.

The Examiner has rejected to claims 1-21 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. The Examiner alleges that the amendments to the claims submitted on February 2, 2006 contained new matter. In making the rejection the Examiner refers to the background of the invention, the significance of referring to the recitations of this section of the specification is unclear. In any event, to the issue of support for the added claim language, the Examiner is directed to the second full paragraph of the detailed description where it states:

> As shown in Fig. 1 both the first and second flanges have a curved shape. This curved shape opposes movement of the transtracheal stent after it has been implanted in a patient. The shape of the first flange 12 approximates the curvature of the patients neck, this has the benefit of avoiding unnecessary obtrusion from the patient's neck and providing for a relatively comfortable resting point of the device. The first flange may also be equipped with holes 18 for securing the stent 10 to the patient through the use of sutures or other surgical securing means. The curvature of the second flange 14 acts against the interior of the trachea to prevent the inadvertent removal of the stent 10 from the patient.

It is submitted that this portion of the specification provide ample support for the phrase "a first flange operable to be placed on the neck of the patient and having an opening therein." Withdrawal of the rejection is requested in view of the express teachings of the specification.

Next, on the merits, the office action rejects claims 1 and 4 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,614,516 to Blom et al.

As an initial matter, Blom does not teach an implantable "transtracheal" surgical device. Blom is directed to a device having one flange on a patient's neck and a second inside the patients esophagus. To accommodate such a device, the trachea must first be removed. Even ignoring the requirement that the device of Blom necessitates the removal of the trachea, the structure of the second flange of Blom is inherently different due to its placement in the esophagus. The tracheal wall is stiff, supported by cartilaginous rings and the mucosal surface

is easily affected by foreign bodies which usually fosters crusting and erosion of the surface itself. In contrast, the esophageal wall is flexible, elastic and forgiving to intrusions of foreign bodies. Those of skill in the surgical arts are well aware of the distinctions of such devices and the differing requirements for implantation. A device implantable in the esophagus such as shown in Blom is not, contrary to the Examiner's suggestion, implantable in the trachea of a patient. Those of skill in the art readily recognize this difference and would recognize that "operable to be placed in the trachea" is much more than an intended use and connotes many of the technical requirements of such a device. Moreover, claim 1 has been amended to recite "an implantable transtracheal surgical apparatus," it is submitted that as Blom teaches an esophageal device it does not teach a transtracheal device.

Still further, contrary to the Examiner's suggestion, the device shown in Blom cannot receive an oxygen supply line, as recited in independent claim 1. Introduction of an oxygen supply line would force the valve 28 leading to the esophagus open and thus result in the introduction of oxygen to the esophagus, not the trachea, which can have very undesirable effects on the patient. Accordingly, one of skill in the art would rarely insert an oxygen supply line into a esophageal device.

Finally, there is no teaching in Blom of a device with flanges having opposing curvatures. These opposing curvatures result in a device that is essentially self anchoring. The device in Blom is not self anchoring as evidenced by the tapes shown in Figs 1 and 4, which are a commonly known method of securing implantable devices.

Accordingly, it is submitted that independent claim 1 patentably distinguishes over the relied upon portions of Blom and is allowable.

Next the Examiner rejects claims 1, 5, and 12 as anticipated under 35 U.S.C. § 102(b) by U.S. Patent Application No. 2002/0092526 to Bertoch.

It is respectfully submitted that Bertoch teaches nothing more than a "bite block" intended to be gripped by a users teeth. Bertoch does not teach an implantable transtracheal surgical device or a transtracheal oxygen supply line. As discussed above, the word transtracheal is not an intended use but rather gives life and meaning to independent claims 1 and 12. Both the location of the implantation of the device, and its interaction with the living surfaces at such an implantation location are clearly conveyed by the term "transtracheal." Accordingly, because Bertoch does not teach each and every limitation of independent claims 1 and 12 it is submitted that these claims patentably distinguish over Bertoch and are allowable.

The Examiner has also rejected dependent claims 1-11, and 13-21 as unpatentable over the combination of one or more of Bertoch in view of U.S. Patent No. 3,973,569 to Sheridan, U.S. Patent No. 4,325366 to Tabor, U.S. Patent No. 5,251,617 to Linder, U.S. Patent No. 4,246,897 to Muto, U.S. Patent No. 5,287,852 to Arkinstall, U.S. Patent No. 3,659,611 to Miller U.S. Patent No. 5,305,740 to Kolobow, and U.S. Published Patent Application No. 2005/0166924 to Thomas.

It is respectfully submitted that none of these references overcomes the shortcomings of either Blom or Bertoch as described above. Moreover, it is submitted that many of these references fail to teach that for which the Examiner cites them. For example, there is nothing in Sheridan to suggest that the flanges are arranged 90° apart from each other. Contrary to the Examiner's assertion the flanges are to be wired to each other thus despite being slidable, the flange are intended to mirror each other to provide a secure anchor. Moreover, both flanges in Sheridan are external to the patient. The device described in Tabor remains at all times external

to the patient, thus it is not analogous to an surgically implantable device, and is not a proper reference for combination here. Arkinsall does not teach a "bushing" as alleged by the Examiner, but rather a threaded connection that impinges on the skin of the patient using a washer. As to the teaching of Miller, the alleged "opposedly curved' disks are all internal to the trachea, any flange on the exterior of the patients neck are shown as flat and not curved.

Accordingly, it is submitted that dependent claims 2-9, 11, 13-19, and 21 which are dependent from one of the allowable independent claims discussed above are therefore believed patentable for at least the same reasons. Because each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

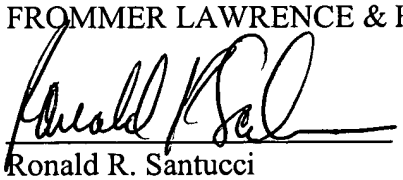
In the event that the Examiner disagrees with any of the foregoing comments concerning the disclosures in the cited prior art, it is requested that the Examiner indicate where in the reference, there is the basis for a contrary view.

CONCLUSION

Please charge any additional fees that may be needed, and credit any overpayment, to our Deposit Account No. 50-0320.

In view of the foregoing amendments and remarks, it is believed that all of the claims in this application are patentable and Applicants respectfully request early passage to issue of the present application.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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